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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,638	04/26/2001	Scott J. Davis	P-9596.00	9208
27581	7590	05/19/2004		
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			EXAMINER DROESCH, KRISTEN L	
			ART UNIT 3762	PAPER NUMBER

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/843,638	DAVIS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kristen L Drosch	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 4/12/04 (amendment).
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-9,13-30 and 34-45 is/are pending in the application.
- 4a) Of the above claim(s) 20-23,26,29,30,35 and 43 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9,13-19,25,27,28,34,36-42,44 and 45 is/are rejected.
- 7) Claim(s) 24 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 01 May 2002 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 20-23, 26, 29-30, 35, and 43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5, 8-9, 13-19, 25, 27-28, 34, 36-37, 40-42, 44-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Romkee (5,603,730).

The statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

With respect to claims 1, and 13, Romkee shows a implantable therapy delivery device; a therapy delivery element (14); an adjustable anchor (24) coupleable to the therapy delivery element, the adjustable anchor being implantable and including a therapy grip element (50) configured to be actuated to at least one of an open position or a closed position, the therapy grip element having a first portion (left shaded area in picture below) and a second portion (right shaded portion in picture below), wherein in the open position the grip element comprises a discontinuous inner surface and the first portion is separated from the second portion by a first distance, and wherein in the closed position the first portion is separated from the second portion

by a second distance less than the first distance and the inner surface is configured to grippingly engage the therapy delivery element, at least two extension elements (32, 34) connected to the therapy grip element extending perpendicularly from the therapy delivery element and configured to actuate the therapy grip element, and a tissue fixation element (86, 88) connected to the extension elements and configured to be fixed to a tissue location from an axial direction to the therapy delivery element (Col. 2, line 65-Col. 3, line 1; Fig. 3).

Regarding claims 2, 14, 36, and 44, Romkee shows the tissue location is near where the therapy delivery element enters the human body on subcutaneous tissue (Col. 3, lines 32-35, Fig. 1).

With respect to claims 3, 15, 37, and 45, Romkee shows the two extension elements (32, 34) are actuated with a single pincer motion (Fig. 5).

Regarding claims 4-5, and 40-41, Romkee shows the therapy delivery system is an electrical lead and a catheter.

With respect to claim 16, Romkee shows the therapy grip element has a substantially rigid grip surface.

Regarding claim 17, Romkee shows the therapy grip element is configured in a normally closed position (Col. 2, line 65-Col. 3, line 24).

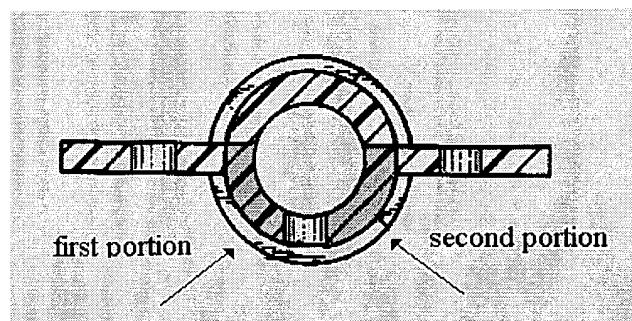
With respect to claims 18-19, Romkee shows the therapy grip element (50) covers at least about 25 and 270 degrees of the therapy delivery element (Fig. 3).

Regarding claim 25, Romkee shows the extension element is positioned at less than about 180 degrees in relation to the therapy delivery element (Figs. 3, 5).

With respect to claim 27, Romkee shows the tissue fixation element (86, 88) has a suture fixation configuration (Col. 2, lines 59-60).

Regarding claim 28, Romkee shows the tissue fixation element is configured at a predetermined position in relation to the extension element (Fig. 2).

With respect to claims 34, and 42, Romkee shows a method comprising inserting the therapy delivery element into a human body, separating a first portion (left shaded area in picture below) of a therapy grip element (50) from a second portion (right shaded area in picture below) of a therapy grip element (50) to form a discontinuous inner surface of the therapy grip element by actuating the extension elements to open the therapy grip element; placing the therapy element within the inner surface of the therapy grip element; positioning the therapy grip element at a grip location on the therapy delivery element, closing the therapy grip element by actuating the extension elements such that the inner surface of the grip element grippingly engages the therapy deliver element; securing the therapy grip element on the therapy delivery device when the therapy grip element is closed, positioning a tissue fixation element at a tissue location, and fixing the tissue fixation element to the tissue at the tissue location in an orientation along the axial length of the therapy delivery element, and connecting the therapy delivery element to the therapy delivery device (Col. 3, lines 10-47; Fig. 3).



***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6-7, and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Romkee (5,603,730). Romkee discloses the claimed invention except for the implantable therapy delivery device being a neurostimulator or therapeutic substance delivery device. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the implantable therapy delivery device as taught by Romkee with a neurostimulator or therapeutic substance delivery device, since applicant has not disclosed that this particular implantable therapy delivery device provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any implantable therapy delivery device such as the defibrillator taught by Romkee for defibrillating the heart.

***Response to Arguments***

6. Applicant's arguments filed 4/12/04 have been fully considered but they are not persuasive. The examiner disagrees with applicant's position that the sleeve of Romkee has a continuous inner surface in the open position. In Figure 3, Romkee shows a discontinuous inner surface since there is an opening that allows for the sleeve to flex; the opening provides the discontinuity in the surface.

***Allowable Subject Matter***

7. Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to teach or suggest an adjustable anchor comprising a therapy grip element configured to be actuated to at least one of an open position or a closed position, the therapy grip element having a first portion and a second portion, wherein in the open position the grip element comprises a discontinuous inner surface and the first portion is separated from the second portion by a first distance, and wherein in the closed position the first portion is separated from the second portion by a second distance less than the first distance and the inner surface is configured to grippingly engage the therapy delivery element, at least two extension elements connected to the therapy grip element extending perpendicularly from the therapy delivery element and configured to actuate the therapy grip element, and a tissue fixation element connected to the extension elements and configured to be fixed to a tissue location from an axial direction to the therapy delivery element; all in combination with the therapy grip element having a grip stop surface that engages a complimentary extension stop surface to prevent the extension element from actuating the therapy grip element beyond a desired actuation limit.

***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Drosch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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